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Mammotome® Hand Held 8 Gauge Probe 510(k) Summary of Safety and Effectiveness

K003297

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Dennis Hahn
Manager, Regulatory Affairs

Date Prepared:
October 2, 2000

Name of Device
Trade Name: Mammotome® Hand Held 8 Gauge Probe
Classification Name: Biopsy Needle

Predicate Devices:
Mammotome® Hand Held System
Mammotome® Biopsy System
AutoSuture® ABBI® System

Device Description
The Mammotome® Hand Held Probe is a sterile, single patient use instrument which may be used with imaging guidance, such as ultrasound, in conjunction with the Mammotome® System, to excise a diagnostic sample for diagnosis. It is designed to be loaded into the Mammotome® Hand Held Holster and Cables. The probe consists of an outer trocar shaft, a telescoping inner hollow coaxial cutter and a knockout tube. The probe incorporates a distal sample notch and a proximal specimen collection chamber. The body of the probe contains a locking tab to secure the probe into the holster. Aspiration conduits are integrated into the probe to allow for connection to an aspiration source. The probe performs the commands issued through the control buttons on the Holster/Cable assembly or through the footswitch attached to the control module.

Intended Use

The Mammotome® Hand Held Probe is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Technological Characteristics

The Mammotome® Hand Held 8 Gauge Probe is a modification of the currently marketed Mammotome® Hand Held 11 Gauge Probe. The modified device incorporates a larger diameter cutter and a bladed tip.

Performance Data

Preclinical testing was performed to ensure the device performs as intended. Testing demonstrated satisfactory performance in breast tissue biopsy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Dennis Hahn
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K003297
Trade Name: Mammotome® Hand Held 8 Gauge Probe
Regulatory Class: II
Product Code: KNW
Dated: October 2, 2000
Received: October 20, 2000

Dear Mr. Hahn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003297

Device Name: Mammotome® Hand Held 8 Gauge Probe

Indications for Use:

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Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

for Mark N Milkuson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003297